

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV724616 US

Express Mail Label Number

November 30 2005

Date of Deposit

Form PTO-1390-MOD
(REV 10-96)

U. S. Department of Commerce Patent and Trademark Office

ATTORNEY'S DOCKET NUMBER

BP/G-32574A

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

10/520,569

INTERNATIONAL APPLICATION NO.

PCT/EP03/07347

INTERNATIONAL FILING DATE

8 July 2003 (08.07.03)

PRIORITY DATE CLAIMED

9 July 2002 (09.07.02)

TITLE OF INVENTION

LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

APPLICANT(S) FOR DO/EO/US

BETZ ET AL.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau. (See Form PCT/IB/308)
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An executed Declaration and Power of Attorney (original or copy) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included.

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the International application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: As stated in our Petition Under 37 CFR 1.47(a) filed on November 29, 2005, Applicants are providing English language translations of Mr. Betz's Letter and Dr. Gasteiger's Letter.

RECEIVED

27 JAN 2006

Legal Staff
International Division

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)
10/520,569

INTERNATIONAL APPLICATION NO.
PCT/EP03/07347

ATTORNEY'S DOCKET NUMBER
BK 2574A

The following fees are submitted:

21. ☐ Basic national fee. \$
22. Examination Fee
☐ If International preliminary examination report was prepared by USPTO
and all claims satisfy provisions of PCT Article 33(1)-(4) \$
☐ All other situations. \$
23. Search fee
☐ If Search fee (37 CFR 1.445(a)(2)) has been paid on the international
application to the USPTO as an International Searching Authority. \$
☐ If International Search Report was prepared and provided to the Office. . . \$
☐ All other situations. \$

CALCULATIONS PTO USE
ONLY

TOTAL OF 21, 22 AND 23 =

\$

Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
- 100 =	/50 =	X	\$ 250	\$

Surcharge of \$130 for furnishing the oath of declaration later than ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).

\$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	- 20 =	X	\$ 50	\$
Independent claims	- 3 =	X	\$ 200	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+	\$ 360	\$

TOTAL OF ABOVE CALCULATIONS =

\$

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).

\$

SUBTOTAL =

\$

Processing fee of \$130 for furnishing the English translation later than ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).

\$

TOTAL NATIONAL FEE =

\$

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property

\$

TOTAL FEES ENCLOSED =

\$

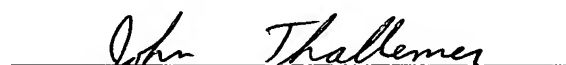
Amount to be: refunded	\$
charged	\$

- a. ☐ A check in the amount of \$_____ to cover the above fees is enclosed.
- b. ☒ Please charge Deposit Account No. 19-0134 in the name of Novartis in the amount of \$_____ to cover the above fees. A duplicate copy of this form is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0134 in the name of Novartis.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

Send all correspondence to the address associated with Customer No. 001095, which is currently:

Novartis
Corporate Intellectual Property
One Health Plaza, Building 104
East Hanover, NJ 07936-1080


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(862) 778-7945

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27 JAN 2004

Dr. Michael Betz, Jaegerstrasse 1, CH 8200 Schaffhausen

Bljana Colovic
Novartis AG
Corporate Intellectual Property
4002 Basel

Legal Staff
International Division

Schaffhausen, 17th December 2003 (2004)

Patent applications: Liquid formulations with high concentrations of human growth hormone (HGH), containing 1,2-propylene glycol/ glycine / phenol

Dear Frau Colovic,

Thank you for sending the declarations of assignment. It give me great pleasure to see that my inventions will be put to commercial use.

I have in my possession three sets of documents:

- One dated 6th August 2003, already signed by John Stevens, in respect of patent applications BP/G-32574P1; BP/G-32575P1 and BP/G-32576P1;
- one dated 10th December 2004, in respect of patent applications BP/G-32575A/BCK and BP/G-32576A/BCK (National Phase PCT/EP03/07349 and PCT/EP03/07346); and
- one dated 14th December 2004 in respect of patent application BP/G-32574BCK (National Phase PCT/EP03/07347).

In all the letters, I am requested to sign the said documents and thereby surrender to Sandoz AG all my rights in connection with these inventions.

In addition, there is my letter to Mr. Thomas Lehmeier of 1st September 2003, to which I have not yet received a reply.

In my letter, I pointed out *inter alia* §§ 7 to 17 of patent law, in which the Austrian legislation on the technical area of the patent relates expressly to the so-called service invention. When weighing up the interests between the employer and the employee inventor in the commercial evaluation of his invention, patent law operates on the principle that the result of work, in other words the invention of the employee, is not to be assigned for a fee to the employer, but a differential treatment regulation applies.

In any case, the employee is entitled to an appropriate special remuneration in accordance with § 8 para. 1 of patent law, because according to regulations the employee's salary does not count as compensation for inventive activity. The rights of the employee from the invention are unilaterally absolute in his favour according to § 17 of patent law, and remain in force even after termination of employment according to § 16 of patent law.

I'd like to ask you again to explain the facts from your point of view, especially in respect of an appropriate remuneration, since all your correspondence on this point has been very recitent in this respect (we do hereby sell and assign to Sandoz... all our right, title and interest...).

You will understand that I shall let you have the signed documents only after we have reached an agreement.

Yours sincerely,

Dr. Michael Betz

Biochemiestr, 10, 6250 Kundl, Austria

From Dr. Peter Gasteiger
Human Resources
Tel +43 (0)5338 200 3283

Email peter.gasteiger
@sandoz.com

Date 17th May 2005

Dr. Michael Betz
Jägerstraße 1
CH-8200 Schaffhausen

Patent application

Dear Dr. Betz,

We have been told by the Novartis Corporate Intellectual Property Department in Basel that you have not yet signed the documents for filing a patent application for certain liquid formulations with high concentrations of human growth hormone.

At this point, we would politely request you to do so by return. Regarding the claim for reimbursement which you have put forward, we would like to remind you of the two conditions for this:

1. Existence of patentability, established by grant of patent
2. a commercial act of use by the (former) employer.

Neither exists at present; in particular, we do not envisage when commercialisation will take place. When the conditions apply, we will examine any claims you may have for reimbursement in accordance with the provisions of patent law.

Furthermore, we would point out that Sandoz reserves the right to legally enforce if necessary any additional costs incurred by your refusal to sign the afore-mentioned documents. If the non-signing should also result in the loss of a patent application, Sandoz will present you with a statement of claim for damages - after appropriate verification. We presume that it will not come to this, and request your co-operation. Thank you!

Yours sincerely

Sandoz GmbH

Dr. Peter Gasteiger